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TESTING AND EVALUATION OF THE BAYER CORPORATION GLUCOSE METER, MODEL ENCORE 5885a

MSgt Butch O. Blake

AIR FORCE RESEARCH LABORATORY
HUMAN EFFECTIVENESS DIRECTORATE
BIODYNAMICS & PROTECTION DIVISION
SYSTEMS RESEARCH BRANCH
2504 Gillingham Dr., Ste 25
Brooks AFB, Texas 78235-5104

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Butch O. Blake

BLAKE, BUTCH O., MSgt, USAF
NCIOC, Air Force Medical Equipment
Development Laboratory

James C. Sylvester

JAMES C. SYLVESTER, Major, USAF, NC
Chief, Air Force Medical Equipment
Development Laboratory

Roger L. Stork

ROGER L. STORK, Colonel, USAF, BSC
Chief, Biodynamics Protection Division

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Butch O. Blake, MSgt

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Air Force Research Laboratory
Human Effectiveness Directorate
Biodynamics Protection Division
2504 Gillingham Dr. STE 25
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The Bayer, Corporation Glucose Meter, Model Encore 5885A is a hand-held, lightweight, compact, blood glucose monitoring system. The EUT provides an easy way for patient's to test blood for glucose in the home or professional use. The EUT operates in a metered range between 10 – 600 mg/dl. It has the ability to store up to 10 recent blood glucose test results and provide an average of all stored tests. The EUT operates off of two internal, non-replaceable lithium batteries, which will complete approximately 15,000 tests. After the batteries expire the EUT then becomes disposable. The EUT weighs approximately 0.38 lbs. with internal batteries and case. Its dimensions are 2.5 in. W. X 4.38 in. H. X 0.88 in. D.

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TESTING AND EVALUATION OF THE BAYER, CORPORATION GLUCOSE METER, MODEL ENCORE 5885A

BACKGROUND

Headquarters Air Mobility Command (AMC) requested the Air Force Medical Equipment Development Laboratory's (AFMEDL) participation in evaluating and approving the Bayer Corporation, Glucose Meter Model Encore 5885A for use on board USAF aeromedical evacuation aircraft. Specific components of the Bayer Corporation, Glucose Meter Model Encore 5885a that under went the evaluation process included: the Bayer Corporation basic unit S/N: 1617569. Throughout this report, the term Equipment Under Test (EUT) refers to the model Encore 5885A.

DESCRIPTION

The EUT is a hand-held, lightweight, compact, blood glucose monitoring system. The EUT provides an easy way for patient's to test blood for glucose in the home or professional use. The EUT operates in a metered range between 10 – 600 mg/dl. It has the ability to store up to 10 recent blood glucose test results and provide an average of all stored tests. The EUT operates off of two internal, non-replaceable lithium batteries, which will complete approximately 15,000 tests. After the batteries expire the EUT then becomes disposable. The EUT weighs approximately 0.38 lbs. with internal batteries and case. Its dimensions are 2.5 in. W. X 4.38 in. H. X 0.88 in. D. (Figure 1).

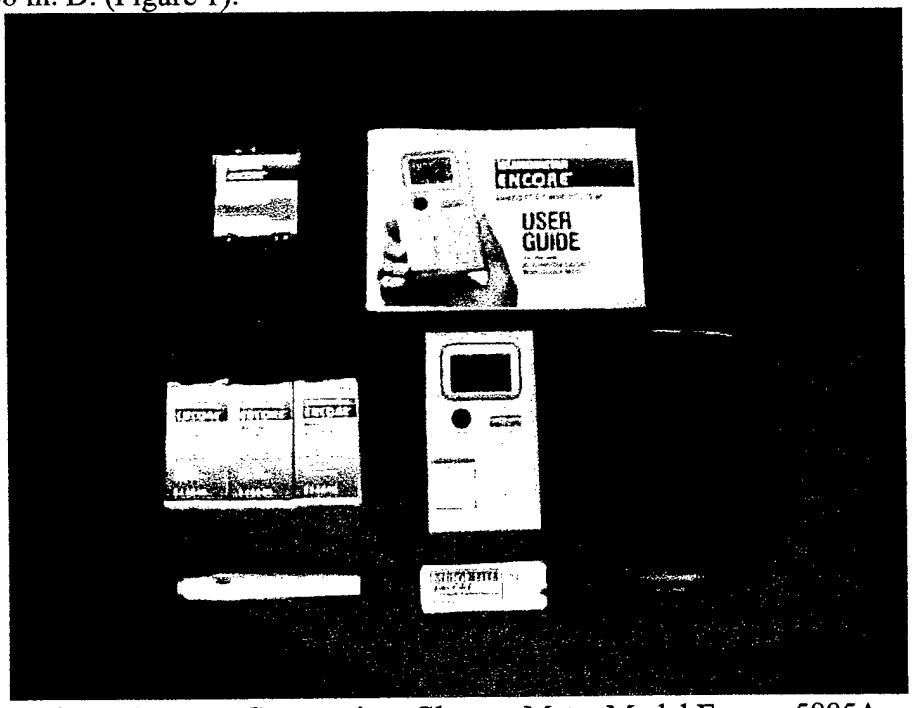

Figure 1. Bayer Corporation, Glucose Meter Model Encore 5885A

PROCEDURES

Test methods and performance criteria were derived from nationally recognized performance guidelines (1 & 2), military standards (3-7), and manufacturer's literature (8). The AFMEDL Procedures Guide describes additional safety and human interface issues to be considered during equipment testing (9). A test setup and performance check was developed specific to this EUT to verify its proper functioning under various testing conditions. All tests were conducted by (AFMEDL) personnel assigned to the Systems Research Branch, Biodynamics and Protection Division, Human Effectiveness Directorate, Air Force Research Laboratory, Brooks AFB, Texas unless otherwise noted.

The EUT was subjected to various laboratory and in-flight tests to observe and evaluate its performance under anticipated operational conditions.

1. Initial Inspection

2. Electromagnetic Interference (EMI)

3. Thermal/ Humidity Environmental Conditions, encompassing:

    a. Hot Operation

    b. Cold Operation

    c. Humidity Operation

    d. Hot Temperature Storage

    e. Cold Temperature Storage

4. Hypobaric Conditions

    a. Cabin Pressure/Altitude

    b. Rapid Decompression to simulated flight level

5. Airborne Performance

INITIAL INSPECTION AND TEST PREPARATION

a. The EUT was inspected for quality of workmanship, production techniques and pre-existing damage.

b. The EUT was checked to ensure it met safety requirements and operating

characteristics established in National Fire Protection Agency (NFPA) 99 (1), AFI 41-201, Equipment Management in Hospitals (3).

c. The EUT was examined to ensure it met basic requirements for human factor design as outlined in MIL-STD 1472E (4).

d. A test setup and performance check was developed to evaluate the EUT's operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP

The EUT was prepared for tests as follows:

1. Placed EUT on a level surface
2. Turned EUT on
3. Assessed proper operating code (P-5 calibration paddle or P-7 test strip)
4. Depressed test slide release to open test strip bay
5. Inserted test strip or calibration paddle
6. EUT completes test procedure and displays value on liquid crystal display (LCD).

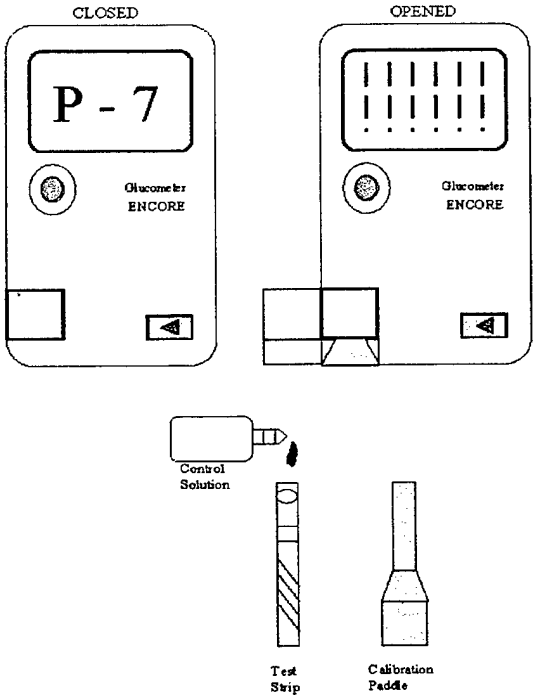

Figure 2. Test Setup

PERFORMANCE CHECK

The following performance check was used to validate the function of the EUT during each of the following test conditions:

1. Turn EUT on by pushing in the on/off button located at the lower left corner of LCD and wait for EUT to perform a self-test.
2. Input proper operation code by depressing on/off button until proper code is displayed.
3. Depress test slide release to open test strip bay, and insert test strip with high or low control fluid or calibration paddle into test strip bay.
4. The LCD on EUT will verify the input parameters.

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility testing is a primary concern on USAF aeromedical evacuation aircraft. Safety is the driving factor to assessing the effects of excessive electromagnetic interference (EMI) emissions and potential influence on aircraft navigation and communications equipment. Medical devices may be susceptible to fields generated by aircraft equipment and malfunction in their presence.

The EUT was evaluated for compliance with MIL-STD-461D & MIL-STD-462D (6 & 7). ASC/ENAI engineers at Wright-Patterson AFB evaluated the electromagnetic compatibility data and determined the airworthiness of the medical device. Specific tests conducted were as follows:

a. Radiated Emissions (RE-102), "Radiated Emissions, Electric Field, 10 kHz to18 GHz.": For Air Force aircraft applications, radiated emissions were tested in a narrower range of frequencies from 2 MHz - 1 GHz. This test measured the amount of EMI emitted by the EUT during operation. It verifies the EUT's potential to affect other equipment susceptible to electromagnetic emissions (i.e., aircraft navigation and communications equipment).

b. Radiated Susceptibility (RS-103), "Radiated Susceptibility, Electric Field, 10 kHz to 40 GHz.": For Air Force aircraft applications, radiated susceptibility was tested in a narrower frequency range from 30 MHz - 12.4 GHz at the following field strength levels: 20 V/M below 1 GHz and 60 V/M above 1 GHz (MIL-STD-461D field strength values from Table IV, Category, Aircraft Internal). This test evaluated the EUT's resistance to predefined levels of EMI generated by antennas both internal and external to the aircraft.

During emissions testing, all EUT's electrical components were operating for the duration of the test to create the worst case emissions scenario. In these tests, the EUT was programmed to continuously analyze the calibration paddle. For both emissions and susceptibility testing, the EUT was tested for operation using internal battery power.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

Extreme temperature and humidity testing determines if aeromedical equipment can be stored and operated during severe environmental conditions without experiencing physical

damage or deterioration in performance (5). Extreme environmental conditions can have incapacitating effects on medical equipment including the following: changes in material characteristics and material dimensions, overheating, changes in lubricant viscosity, corrosion, changes in electronic components, and electronic or mechanical failures due to rapid water or frost formation.

Testing was conducted in the calibrated Thermotron Industries, model SM-32 environmental chamber. The EUT was placed in the center of the environmental chamber. The other components of the test setup remained outside the chamber. For operational tests, the EUT was monitored continuously, and a performance check was conducted every 15 minutes. For storage tests, the EUT was placed in the chamber and remained non-operational throughout the storage portion of the test. The following describes the conditions of the environmental tests performed:

a. Humidity: 94 ± 4% RH, 85°F ± 3.6°F (29.5°C ± 2°C) for 4 hr

b. Hot Temp Operation: 120°F ± 3.6°F (49°C ± 2°C) for 2 hr

c. Cold Temp Operation: 32°F ± 7.2°F (0°C ± 4°C) for 2 hr

d. Hot Temp Storage: 140°F ± 3.6°F (60°C ± 2°C) for 6 hr

e. Cold Temp Storage: -40°F ± 3.6°F (-40°C ± 2°C) for 6 hr

HYPOBARIC CONDITIONS

Cabin Pressure/Altitude: Altitude testing is critical for aeromedical evacuation equipment due to potential effects of barometric pressure changes on the equipment. A majority of the aircraft characterized as opportune aircraft available for use in aeromedical evacuation, pressurize their cabins to barometric pressures equivalent to 8,000 - 15,000 ft above sea level. The differences in pressures affect the operation of some medical equipment. Altitude testing consisted of operating the EUT while ascending from ground level to 15,000 ft; stopping at 2,000 ft increments for performance checks. The rates of ascent and descent were 500 ft/min.

Rapid Decompression Testing: A rapid decompression (RD) is the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressures. It is important to assess medical equipment functioning during and after RD so as not to endanger patients, personnel, or the aircraft. The EUT operated inside the rapid decompression test chamber as the chamber was pressurized to an equivalent of 8,000 ft altitude. Then the chamber altitude was brought to 45,000 ft over a period of 60 seconds, held at 45,000 ft for a few minutes, and then returned to ground at a rate of 10,000 - 12,000 ft/min. The test was repeated twice more; once for a 7 second RD and once for a 1 second RD. The EUT was monitored throughout the series of decompressions. Performance checks were assessed each time the EUT returned to ground level.

AIRBORNE PERFORMANCE

Airborne performance evaluations are a cost-effective and invaluable means of validating clinical and operational suitability of medical equipment items under actual operating conditions. In-flight test and analysis demonstrates the EUT's ability to provide patient care onboard USAF aircraft. Safe and reliable operation is the primary goal of the in-flight evaluation and forms the basis for subsequent recommendations to the users.

Flight qualified AFMEDL aeromedical crewmembers flying on C-9 aeromedical evacuation mission conducted this phase of testing. The EUT was taken out of its protective case and used in various areas of the aircraft. Then human factor characteristics were evaluated, e.g., securing methods, setup/tear down times and securing locations evaluated. Feedback from other aeromedical evacuation crewmembers was obtained concerning EUT human factor considerations.

EXPLOSIVE ATMOSPHERE

The purpose of this test is to demonstrate the ability of the EUT to operate in a flammable atmosphere (fuel vapor-laden environment) without causing and explosion. The EUT was evaluated for compliance with MIL-STD-810E (5). WRACC/TIECD engineers at Robins AFB, GA evaluated the explosive atmosphere test data and determined the medical device did not pose an explosive atmosphere hazard.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection revealed no manufacturing defects. The unit performed to the manufacturer's specification.

ELECTROMAGNETIC COMPATIBILITY

ASC/ENAI, Wright-Patterson AFB certified the EUT for use in aeromedical evacuation system on some U.S. Air Force aircraft (including large body, fixed wing and C-21 Learjet) while operating from internal battery power. However, the EUT was susceptible to electromagnetic fields in the frequency range of 840 MHz – 2.66 GHz. During RS103 testing the EUT was considered acceptable if the reading on the display remained between 310 – 318, with a normal reading being 314 – 315. However, during the above mentioned frequency range the EUT varied more than 3 – 4 units beyond 310 – 318 and the readout would typically change to dash lines failing to analyze. Upon electromagnetic field removal the EUT would recover and function normally. AFMEDL personnel conducted an actual field test using a C-21 Learjet from the 458th

at Scott AFB, IL. The assessment was performed on the ground using a ground power unit to supply power to the aircraft. The IFF and TACAN systems were activated and data was collected at five different points off the nose of the aircraft from a distance of approximately four meters. The evaluation was continued inside the C-21 at stations aft and mid-cabin and in the flight deck. The EUT performed according to manufacturer's specifications. The data was sent to ASC/ENAI for overview and approval. ASC/ENAI concurred with AFMEDLs findings and certified the EUT for use on the C-21 Learjet.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

The EUT was evaluated IAW manufacturer's guidelines regarding hot operation, cold operation, and humidity. The EUT was not designed to handle AFMEDL environmental extremes in those areas. For hot and cold operation testing, the EUT was assessed between 17°C (63°F) and 30°C (86°F). During humidity evaluation the manufacturer's humidity range of 85% Relative Humidity at 30°C (86°F) was used. However, the EUT was able to handle hot storage and cold storage IAW AFMEDL parameters. The EUT operated satisfactory according to manufacturer's guidelines during humidity, hot operation, and cold operation testing. The EUT also operated satisfactory according to AFMEDL guidelines following hot and cold storage.

HYPOBARIC CONDITIONS

1. Cabin Pressure/Altitude: The EUT performed in accordance with manufacturer's specifications throughout testing. The unit was able to analyze and display blood glucose levels up to 15,000 ft cabin altitude without system failure using High control solution, low control solution and calibration paddle. The ascent and decent rates used during this evaluation were 500 ft/min.

2. Rapid Decompression: The EUT operated satisfactorily following each decompression event.

AIRBORNE PERFORMANCE

The in-flight evaluation of the EUT was performed on a C-9 aeromedical evacuation mission. First evaluations the EUT experienced readings out of the range of the high control solution. It was determined that taking readings in close proximity to the aircraft bulkhead/skin would affect EUT's ability to give accurate readings due to cold ambient temperatures from the aircraft's air conditioner. When using the EUT in the aircraft exercise good judgement when it comes to operation in the aircraft environment.

EXPLOSIVE ATMOSPHERE

The EUT operated satisfactorily IAW MIL-STD-810E regarding explosive atmosphere testing. The EUT did not ignite the fuel vapor-laden environment nor produce a hazard to patients, aircrew or aircraft.

SUMMARY

AFMEDL found the Bayer Corporation, Glucose Meter Model Encore 5885A to be conditionally acceptable for use on all U.S. Air Force aeromedical evacuation aircraft while operating from internal battery power. Its operation was within the majority of parameters when subjected to electromagnetic interference (EMI), most environmental extremes, simulated cabin altitudes, and explosive atmosphere. It did not produce a hazard to patient or crew during rapid decompression.

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REFERENCES

1. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code

2. Emergency Care Research Institute (ECRI)

3. AFI 41-201, Equipment Management in Hospitals

4. MIL-STD 1472E, Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.

5. MIL-STD 810E, Environmental Test Methods and Engineering Guidelines.

6. MIL-STD 461D, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference.

7. MIL-STD-462 D, Measurement of EMI Characteristics.

8. Bayer Corporation, Glucose Meter Model Encore 5885A, Users Guide.

9. AFMEDL Procedures Guide, Internal Operating Instruction, Systems Research Branch, Air Force Research Laboratory.

APPENDIX
MANUFACTURER'S SPECIFICATIONS OF BAYER, CORPORATION GLUCOSE METER, MODEL ENCORE 5885A

SPECIFICATIONS

General

Size:	2.5 in. W. X 4.38 in. H. X 0.88 in. D
Weight:	0.38 lbs.
Display:	Liquid Crystal Display
Meter Measurement Range:	10 – 600 mg/dl
Memory:	Stores the 10 most recent Blood Glucose test results. Provides average of all stored test results.
Power:	2 Lithium, non-replaceable batteries.
Battery Life:	Up to 15,000 tests
Environmental	Temperature: 17°C to 30°C (operating). Humidity: < 85%.